DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
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This corrected version of the November 27, 2002, Warning Letter was issued on February 25, 2003, to correct an error in the original Warning Letter.

November 27, 2002

CORRECTED WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 07

Jerry Jerome
Chief Executive Officer and Chairman of the Board
Jennie-O Turkey Store
2505 Willmar Avenue SW
Willmar, Minnesota 56201

Dear Mr. Jerome:

On June 6, 2002, investigators from the Wisconsin Department of Agriculture, Trade, and Consumer Protection, acting on behalf of the Food and Drug Administration, conducted an inspection of your medicated feed mill located at 64 North Ninth Street, Barron, Wisconsin 54812. That inspection found significant violations of the Federal Food, Drug, and Cosmetic Act (the Act) and deviations from Current Good Manufacturing Practices (CGMP) regulations as required by Title 21, Code of Federal Regulations (21 CFR).

The inspection found that the use of animal drugs in your feed (sulfadimethoxine, ormetoprim, chlortetracycline, diclazuril and bacitracin methylene disalicylate, monensin, and virginiamycin) does not conform to an approved New Animal Drug Application (NADA) as required by Section 512 of the Act. For this reason, the drugs are unsafe under Section 512 of the Act and thus are adulterated under Section 501(a)(5) of the Act.

The animal feed products noted below are also adulterated within the meaning of Section 501(a)(6) of the Act because they bear or contain new animal drugs but do not conform with an approved NADA. The feeds are thus unsafe under Section 512 of the Act and adulterated under Section 501(a)(6) of the Act.

- TURKEY FEED WITH ~~~ (chlortetracycline) -- The drug level in the feed is labeled as containing 200 g/ton, but the product is labeled with "Indications for Use" (treatment of bluecomb) that correspond to a drug level of 25 mg/lb of bodyweight. See 21 CFR § 558.128(d)(1)(v) and (xiii), copy enclosed.

- TURKEY FEED WITH [redacted](diclazuril and bacitracin methylene disalicylate) – Labeling lacks a required statement "Not for use in hens producing eggs for human consumption." See 21 CFR § 558.198(d)(2), copy enclosed.

- TURKEY FEED WITH [redacted] (sulfadimethoxine and ormetoprim) -- Labeling lacks a required statement to "Withdraw 5 days before slaughter." See 21 CFR § 558.575(d)(3)(iii), copy enclosed.

- TURKEY FEED WITH [redacted] (monensin and virginiamycin) -- The labeling lacks a portion of a required caution statement, specifically, "Some strains of turkey coccidia may be Monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis." See 21 CFR § 558.355(f)(2)(iv), copy enclosed.

The missing labeling statements also cause the TURKEY FEED WITH [redacted](diclazuril and bacitracin methylene disalicylate), TURKEY FEED WITH [redacted] (sulfadimethoxine and ormetoprim) and TURKEY FEED WITH [redacted] (monensin and virginiamycin) animal feed products to be misbranded within the meaning of Section 502(c) of the Act.

The four animal feed products are also adulterated within the meaning of Section 501(a)(2)(B) of the Act for failing to comply with CGMP regulations with regard to the labeling requirements as articulated by 21 CFR § 225.80(b)(2) and the record retention requirements as articulated by 21 CFR § 225.102(b)(2).

Title 21, Code of Federal Regulations § 225.80(b)(2) requires proofread labels to be dated, initialed by a responsible individual, and kept for one year after all the labels from the batch have been used. Your failure to keep these labels for one year as required by the regulation renders the products adulterated under Section 501(a)(2)(B) of the Act.

The State investigators noted that the firm's computer system generates a paper production record that provides a complete traceable history of the manufacturing process for each of the medicated feed products it manufactures. The State investigators noted that the paper production records are discarded after 90 days. Feed Mill Manager William Carroll stated that the records are discarded due to the significant amount of space they take up.

Title 21, Code of Federal Regulation § 225.102(b)(2) requires that the original production record or copy thereof shall be retained on premises for not less than one year. Because your firm has not adhered to this requirement, the

manufactured products are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of animal feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in further regulatory and/or administrative sanctions. These sanctions could include seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your firm's medicated feed license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR § 514.115(c)(2). This letter constitutes official notification under the law. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your reply should be addressed to Compliance Officer Timothy G. Philips at the address on the letterhead.

Sincerely,

David R. Yost
Acting Director
Minneapolis District

TGP/ccl

Enclosures: 21 CFR § 585.575(d)(3)(iii)
21 CFR § 558.128(d)(1)(v)
21 CFR § 558.198(d)(2)
21 CFR § 558.355(f)(2)(iv)